K010795

APR 1 1 2001

OPTICAL SENSORS
INCORPORATED

510(k) Summary of Safety and Effectiveness

Company Name:	Optical Sensors Incorporated
Device Name:	CapnoProbe SL Model 2000
510(k) Sponsor:	Optical Sensors Incorporated 7615 Golden Triangle Drive Eden Prairie, MN 55344
510(k) Contact:	Gary Syring Quality & Regulatory Associates, LLC 800 Levanger Lane Stoughton, WI 53589
Phone:	608-877-2635
Fax:	608-873-7382
Summary Date:	March 14, 2001
Trade Name:	CapnoProbe SL Model 2000
Common Name:	Carbon Dioxide Gas Analyzer
Classification Name:	CFR 868-1400 73CCK Carbon Dioxide Gas Analyzer
Predicate Device:	CapnoProbe-A SL, 510(k) K984579

1.0 Description of Device

The CapnoProbe SL Model 2000 provides a measurement of Sublingual PCO_2. The CapnoProbe SL Model 2000 consists of a disposable sensor and hand held instrument. The disposable sensor contains a fiber optic PCO_2 sensor. The disposable sensor is placed under the tongue for a measurement of Sublingual PCO_2.

This premarket notification addresses modifications to the instrument. The disposable probe is not modified. The basic scientific technology of PCO_2 measurement is not affected. The indications for use are not affected.

7615 GOLDEN TRIANGLE DR.
TECHNOLOGY PARK FIVE
MINNEAPOLIS, MN 55344
PHONE 612 • 944 • 5857
FAX 612 • 944 • 6022

2.0 Intended use of Device

The CapnoProbe SL Model 2000 is indicated for monitoring Sublingual PCO2. It is indicated for use in hospital patients. This device is indicated for use by qualified medical personnel only.

3.0 Technological Characteristics

The technical characteristics of the CapnoProbe SL Model 2000 are measurement of PCO_2 by a fiber optic sensor. The fiber optic PCO_2 technical features of the CapnoProbe SL Model 2000 are the same as the unmodified CapnoProbe-A SL.

4.0 Data Summary

Laboratory data are presented demonstrating the CapnoProbe SL Model 2000 instrument with disposable sensors meet the performance specifications. The laboratory evaluation is the same evaluation applied to the unmodified CapnoProbe-A SL.

5.0 Conclusions

The modifications to create the CapnoProbe SL Model 200 instrument were evaluated. All evaluations indicate the CapnoProbe SL Model 2000 meets performance specifications, all risks are mitigated and the CapnoProbe SL Model 2000 is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2001

Optical Sensors Incorporated
c/o Mr. Gary Syring
Quality & Regulatory Association, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K010795
Trade Name: CapnoProbe SL, Model 2000
Regulatory Class: II (two)
Product Code: CCK
Dated: March 14, 2001
Received: March 16, 2001

Dear Mr. Syring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

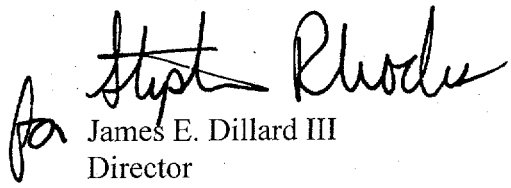
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010795

Device Name: CapnoProbe SL Model 2000 Sublingual CO2 Measurement System

Indications For Use:

The CapnoProbe Sublingual Tonometer System is indicated for monitoring sublingual PCO2. It is indicated for use in hospital patients. This device is indicated for use by qualified medical personnel only.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010795

(Optional Format 3-10-98)